

Marwan as teaching "phenolic compounds that can be isolated from cranberry" thereby resulting in a composition having the same characteristics as the claimed invention.

Applicants respectfully disagree. As amended, the present claims are drawn to compositions comprising a compound *suitable for administering to a subject* and containing a *therapeutically effective amount* of a compound isolated from cranberry. This is a highly desirable feature of the claimed compositions because it makes them especially well suited for use in food or pharmaceutical applications, for example, for the maintenance of good health or treatment of a disease or condition in a human or other animal, as taught in Applicants' specification.

In contrast, Marwan merely identifies and isolates hydroxycinnamic acid derivatives in cranberry for research purposes, such as HPLC (high performance liquid chromatography) analysis and, thus, does not disclose an isolated compound which is sufficiently pure or suitable for administering to a subject, much less a compound in an amount that is therapeutically effective, as claimed by Applicants. Indeed, the authors acknowledge that the purpose of their work is merely "to identify the different hydroxycinnamic acid derivatives in cranberries" (page 774, col. 2, lines 8-9). The authors also acknowledge that some techniques employed even resulted in the partial destruction of the compound ("Treatment with 2N HCl at 80°C for 1 hr caused some destruction of the liberated hydroxycinnamic acid." page 775, col. 1, lines 7-8). Still further, the authors state that to analyze these compounds they must be mixed with a vehicle comprising acetonitrile and formic acid (see, e.g., Fig. 1 legend, page 775, col. 2). Clearly, the authors have prepared samples only for research purposes and in amounts suitable only for chemical analysis and not in therapeutically effective amounts of sufficient purity for administering to a subject.

Accordingly, the compound taught by Marwan is neither suitable for administering to a subject nor in an therapeutically effective amount, as claimed by Applicants. Thus, Applicants respectfully request that the rejection under 35 U.S.C. §102(b), be withdrawn.

#### ***Rejection of Claims 11 and 14 Under 35 U.S.C. §102(b)***

The Examiner rejects claims 11 and 14 under 35 U.S.C. §102(b) as being anticipated by the Merck Index (Budavari *et al.*, Eds., (1989), Entry 2300, page 358). The Examiner characterizes the Merck Index as teaching that cinnamic acid is a known compound (but not that it can be isolated from a cranberry), thereby anticipating the compositions of the claimed invention.

Applicants respectfully disagree. As stated above, the presently claimed invention is drawn to an composition *suitable for administering to a subject* which comprises a compound

*in a therapeutically effective amount isolated from cranberry.* In particular embodiments, the composition can comprise a phenolic, such as cinnamic acid, which is isolated from cranberry.

In contrast, the Merck index teaches a *synthetic* cinnamic acid. Because the compound is synthetic, it is clearly not isolated from cranberry, as claimed by Applicants. Moreover, the synthetic cinnamic acid is useful for industrial purposes only, and thus, is not suitable for administering to a subject in the form of a composition, as claimed by Applicants. Indeed, at page 358, col. 1, the reference states that the main use for synthetic cinnamic acid is the manufacture of esters for the perfume industry. Moreover, it is well known in the art that compounds synthesized and prepared for industrial uses are rarely suitable for administering to a subject. Still further, the Merck index *fails to teach any therapeutic characteristic of cinnamic acid, much less, amounts of cinnamic acid that would be therapeutically effective when administered to a subject.*

Accordingly, because the Merck Index fails to teach a composition having the features of the claimed invention, *i.e.*, a composition *suitable for administering to a subject* having an cinnamic compound *in a therapeutically effective amount*, Applicants respectfully requests that the rejection under 35 U.S.C. §102(b), be withdrawn.

#### ***Rejection of Claims 11, 14, and 21-23 Under 35 U.S.C. §102(b)***

The Examiner also rejects claims 11, 14, and 21-23 under 35 U.S.C. §102(b) as being anticipated by Camire *et al.* (*J. of Food Protection*, 43:36-37, (1980); hereafter “Camire”). The Examiner characterizes Camire as teaching adding cinnamic acid to cranberry juice, thereby anticipating the claims, in particular, “administration forms” of the claimed invention.

Applicants respectfully disagree. As stated above, the presently claimed invention is drawn to an composition suitable for administering to a subject comprising a *therapeutically effective amount* of a compound isolated from cranberry (*i.e.*, claim 11). In particular embodiments, the compositions can comprise a phenolic, such as cinnamic acid, in a therapeutically effective amount (*i.e.*, claim 14), and be in the form of a foodstuff, dietary supplement, or pharmaceutical (*i.e.*, claims 21-23). These “administration forms” have highly desirable health benefits as taught in Applicants’ specification.

In contrast, Camire teaches the addition of cinnamic acid obtained from Mallinckrodt Chemical Works (*i.e.*, cinnamic acid which is not derived from cranberry) to certain juices to retard their spoilage. Indeed, at page 36, the authors state that “it was considered that cinnamic acid might be an inexpensive, useful alternative for the control of enzymic browning...of fruit juices.” The cinnamic acid used by Camire was obtained from Mallinckrodt Chemical Works and “used without further purification” and dissolved in a “small volume of alcohol to keep it

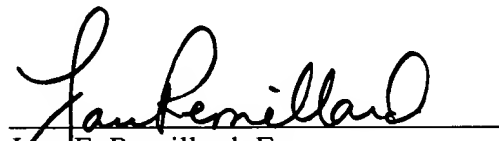
in solution.” Thus, the cinnamic acid used by Camire was *not* purified or prepared in such a way as to make it suitable for administering to a subject, as claimed by Applicants. Rather, cinnamic acid was added to cranberry juice under laboratory conditions to see if it would retard spoilage. Moreover, Camire reports that “[c]innamic acid was found to have no significant effect on anthocyanin stability in cranberry juice” (emphasis added, see Abstract). Accordingly, *Camire fails to teach a therapeutically effective amount of a compound of the invention*, which is, for example, suitable for the maintenance of good health or treatment of a disease or condition in a human or other animal, as taught in Applicants’ specification.

Accordingly, because Camire fails to teach a composition having the features of the claimed invention, *i.e.*, having a compound in a therapeutically effective amount isolated from cranberry and suitable for administering to a subject, for example, in the form of a foodstuff, dietary supplement, or pharmaceutical, Applicants respectfully request that the rejection under 35 U.S.C. §102(b), be withdrawn.

#### **CONCLUSION**

In view of the foregoing, entry of the amendments and remarks herein, reconsideration and withdrawal of all rejections, and allowance of the instant application with all pending claims are respectfully solicited. If a telephone conversation with Applicants’ attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants’ attorney at (617) 227-7400.

Respectfully submitted,

  
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**APPENDIX A**  
**“VERSION WITH MARKINGS TO SHOW CHANGES MADE”**

11. (Amended) A composition suitable for administering to a subject comprising a compound in a therapeutically effective amount isolated from cranberry and selected from the group consisting of a phenolic acid, flavanoid, fiber, omega-3-fatty acid, tocochromanol, triterpenoid, ellagic acid, and combinations thereof.



## **APPENDIX B**

### **Pending Claims**

11. (Amended) A composition suitable for administering to a subject comprising a compound in a therapeutically effective amount isolated from cranberry and selected from the group consisting of a phenolic acid, flavanoid, fiber, omega-3-fatty acid, tocochromanol, triterpenoid, ellagic acid, and combinations thereof.

14. The composition of claim 11, wherein said phenolic acid is selected from the group consisting of para-coumaric acid, caffeic acid, chlorogenic acid, ferulic acid, protocatechuic acid, cinnamic acid, benzoic acid, gallic acid, para-hydroxybenzoic acid, and combinations thereof.

21. A foodstuff comprising a composition according to claim 11.

22. A dietary supplement comprising a composition according to claim 11.

23. A pharmaceutical comprising a composition according to claim 11.